From:	Waltraut Lehmann
To:	Freeburg, Jim (OIC); OIC Rules Coordinator
Subject:	R 2016-22 Prescription drug substitution -- comments on stakeholder draft
Date:	Friday, September 23, 2016 10:00:53 AM

Hello Jim,

Thank you for circulating the stakeholder draft, intended to achieve consistency between Washington's regulations and federal guidance in the HHS 2017 Notice of Benefit and Payment Parameters. The Comments provided to you here are made on behalf of Premera Blue Cross, LifeWise Health Plan of Washington, and LifeWise Assurance Company ("Premera" or "the Companies").

We have identified a provision in the draft that creates significant concerns, and to which we strenuously object. The newly added subsection (6) in WAC 284-43-5080 inserts a process, if a substitution request is denied, for an external review of the denial, if the enrollee requests it. Newly added subsection (7) then states that a denial resulting from such an external review constitutes an adverse benefit determination, which in turn triggers review rights.

Current rule language already provides that, while review of the substitution request is not an appeal process, denial of a substitution request is an adverse benefit determination, thus resulting in the enrollee's rights to the applicable internal and external review steps. The insertion of a second external review step is superfluous and creates a process that is inconsistent with other adverse benefit determination review rights. Such a process would also be administratively burdensome to issuers, and confusing to enrollees, who would be sent back to the issuer to initiate further review.

We have found no basis in the federal provisions to support it, and we, quite candidly, find that it makes no sense at all. In fact, we believe that the rule draft may be based on a mis-reading of the NBPP Final Rule; its preamble clearly explains that there is no intention to have two processes if the state already has an appeals process in place that applies to drug exception requests. Washington has the necessary process. For further reference, I am providing you, below at the end of this message, with the relevant citations.

The Companies believe that the existing Washington rules are clear regarding the review of a substitution denial, and provide all appropriate rights to enrollees, consistent with adverse benefit determinations in general. We respectfully ask that you remove the additional external review process from the draft before proceeding with this rulemaking.

I will be happy to discuss this with you further if that would be beneficial. Please feel free to contact me. Thank you, and best regards,

Waltraut
Waltraut B. Lehmann
Senior Manager, Regulatory Affairs
Premera Blue Cross
425-918-4974

From the NBPP Final Rule preamble:
"As discussed in the 2016 Payment Notice (80 FR 10750), the exceptions process established in this section is distinct from the coverage appeals process established under § 147.136. Specifically, the drug exceptions process applies to drugs that are not included on the plan's formulary drug list, while the coverage appeals regulations apply if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Because these two

processes serve different purposes, we reaffirmed our belief that they are not\ duplicative and we did not propose to change these definitions." (81 Fed. Reg. at 12295)

"We are finalizing our proposal that a State may determine that health plans in the State satisfy the requirements of § 156.122(c) if the health plans have a process through the State's coverage appeals laws and regulations to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan under standards at least as stringent as the requirements at §156.122(c). To meet this standard, the process must include an internal review, an external review, the ability to expedite the reviews, and timeframes that are the same as or shorter than timeframes established under paragraphs (c)(1)(ii) and (c)(2)(iii) of this paragraph. In the event that an exception request is granted under §156.122(c)(4), the excepted drug(s) are treated as an EHB including counting any cost-sharing towards the plan's annual limitation on cost-sharing under §156.130." (81 Fed. Reg. at 12296)

"…We understand that States may not be able to meet these timeframes under their current coverage appeals laws and regulations and that States may have to change their laws and regulations in order to align the timeframes under § 156.122(c), if the State wishes to use its current laws and regulations to streamline processes and create efficiencies…" (*Id.)*